# EMERGING SPINE SURGERY TECHNOLOGIES

## *Evidence and Framework for Evaluating New Technology*

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Quality Medical Publishing, Inc.

ST. LOUIS, MISSOURI

2006

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Printed in Canada

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PUBLISHER Karen Berger
PROJECT MANAGER Donna Rothenberg
EDITOR Michelle Berger
PRODUCTION Carolyn Garrison Reich, Graphic World, Inc.
COVER DESIGN AND ILLUSTRATION Amanda Behr, C.M.I.

Quality Medical Publishing, Inc.
2248 Welsch Industrial Court
St. Louis, Missouri 63146
Telephone: 1-800-348-7808; 314-878-7808
Web site: *http://www.qmp.com*

LIBRARY OF CONGRESS CATALOGING-IN-PUBLICATION DATA

Emerging spine surgery technologies : evidence and framework for evaluating new technology / edited by Terry P. Corbin . . . [et al.].
p. ; cm.
Includes bibliographical references and index.
ISBN 1-57626-138-7 (hardcover)
1. Spine—Surgery. 2. Spine—Surgery—Technological innovations.
3. Surgery—Technological innovations. I. Corbin, Terry P.
[DNLM: 1. Spinal Diseases—surgery. 2. Spine—surgery. 3. Spinal Fusion. WE 725 E53 2006]
RD768.E44 2006
617.4'71—dc22

2005020539

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5 4 3 2 1

Chapter

# 40

# The Raymedica Prosthetic Disc Nucleus: An Update

Charles Dean Ray, M.S., M.D., F.A.C.S., F.R.S.H.(Lond.)

This chapter presents details regarding the anatomy and physiology of the human intervertebral disc, the complex process of progressive disc degenerative disease (DDD) with clinical manifestations, and the need for a disc prosthesis. Details of the research and development of the Prosthetic Disc Nucleus (PDN) are given, along with early clinical applications. Approximately 2500 procedures have now been performed worldwide, and the program is currently in a United States Food and Drug Administration (FDA)–controlled investigational device exemption (IDE) study. The PDN is a definitive, long-term, nonfusion treatment for painful, degenerative spine segmental instability and potentially nucleus replacement where a large herniation has ejected that structure, which not uncommonly leads to late reherniation or degeneration.

Painful DDD with segmental instability has long been a treatment challenge to physicians of many disciplines. At present, among the most popular methods of long-term treatment, beyond conservative, nonoperative treatment, are

Additional studies, conducted at the Institute for Biomechanics, University of Ulm, Germany, evaluated the neutral zone and range of motion in cadaveric lumbar spines before and after nucleus removal and after implantation of the PDN devices. Flexion/extension, lateral bending, and rotation during application of a 200N preload were tested. Although nuclectomy increased the neutral zone and range of motion in all specimens, implantation of the PDN device restored the values to those of the intact state.[29] A similar experiment at Emory showed that the PDN device restored the stiffness (stability) of the enucleated segment to nearly the same as that of the initially intact segment.[26] Clearly, all these tests indicated the PDN to be a safe, durable, and functionally valuable device over its expected life.

## SURGICAL PROCEDURE

Implanted singularly, each PDN-SOLO device comprises a structural polymeric hydrogel pellet constrained by a woven, superhigh-strength, high-molecular-weight polyethylene jacket. The implant is positioned transversely in the enucleated disc space. There is essentially no relative motion between fibers of the jacket so there is essentially no wear.

Implantation of the device is performed through a simple unilateral exposure, as would be used for a discectomy (Fig. 40-2). The annulus is penetrated by a series of dilators, opening but not cutting a path for removal of the nucleus tissue (Fig. 40-3). A rather radical removal of the nucleus is performed (Fig. 40-4), and the evacuated space is estimated using simple measurements plus the injection of radiocontrast medium with the taking of radiographic films, or the use of a fluoroscope. Additionally, sizing instruments are passed through the annulus to estimate the PDN size to be inserted; the largest that can be inserted is used (Fig. 40-5). Insertion and positioning the PDN-SOLO uses a flexible guide, an impactor placed against the trailing end of the PDN, and a traction suture placed before insertion (Fig. 40-6, *A*). This suture aids in positioning the PDN transversely inside the empty nucleus cavity (Fig. 40-6, *B*). During manufacturing, the pellets are dehydrated and mechanically compressed, reducing the volume and profile required to pass through the annular access. Once implanted, the hydrogel absorbs fluid and swells, wedging the device tightly into the cavity and restoring about 1.5 mm in disc height (Fig. 40-7, *A*). The hydration of the implant provides a lifting power similar to that of an intact nucleus (Fig. 40-7, *B*). The pellet contours distribute the load across the endplates.

In many cases, the fully hydrated PDN-SOLO devices resemble essentially normal nuclei (Fig. 40-8).

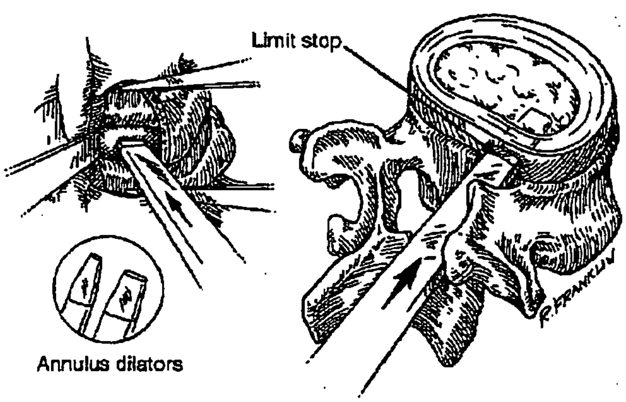



Fig. 40-2 Diagrams of the posterior approach showing the limited laminotomy and stab annulotomy followed by the driving in of a dilator—first a small dilator, then a larger one—to stretch the annular fibers. A Cloward lamina spreader is shown placed in the diagram on the left.

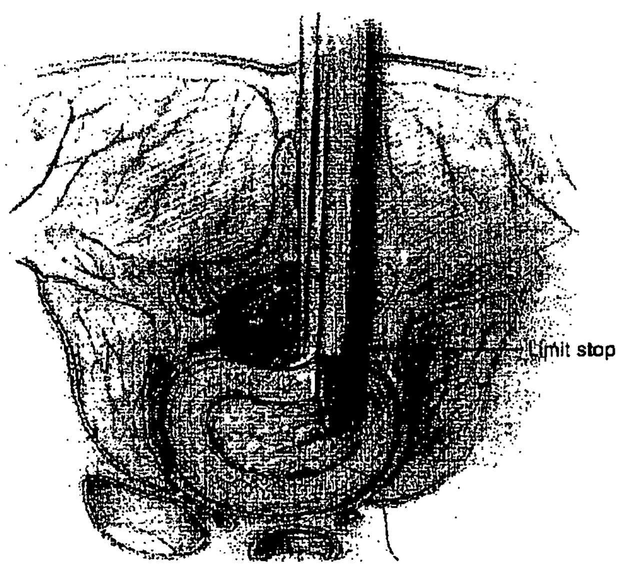



Fig. 40-3 Cross-sectional diagram showing the driven dilator, no further in than the color-changing limit stop to prevent damage to the anterior annulus.

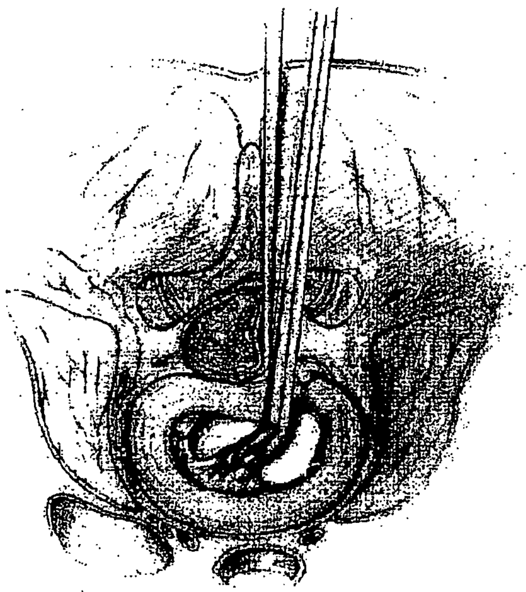


Fig. 40-4 Removal of the nucleus; the posterior contralateral portion being the most difficult to reach. An angulated pituitary rongeur is used. Care must be exercised to not damage the annulus or the endplates during this procedure. Following nucleus removal, an on-table discogram is made and the internal empty volume is estimated. More nucleus tissue removal is usually needed.

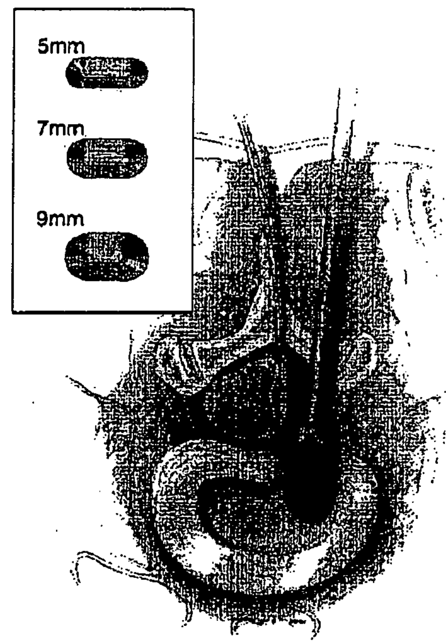



Fig. 40-5 A sizing instrument is used to widen the opening in the annulus and determine the largest PDN that can pass inside. The three heights, 5 mm, 7 mm and 9 mm sizers match the heights of the PDNs used. All PDNs are approximately 28 mm in length. PDN width (12 mm) commands the length of the annulotomy needed.

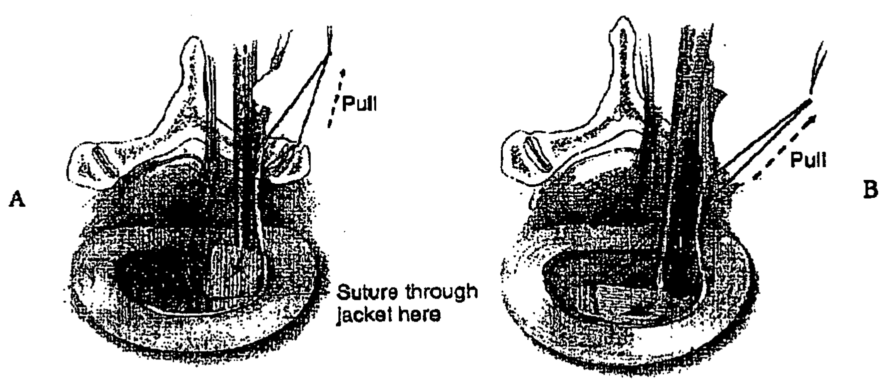
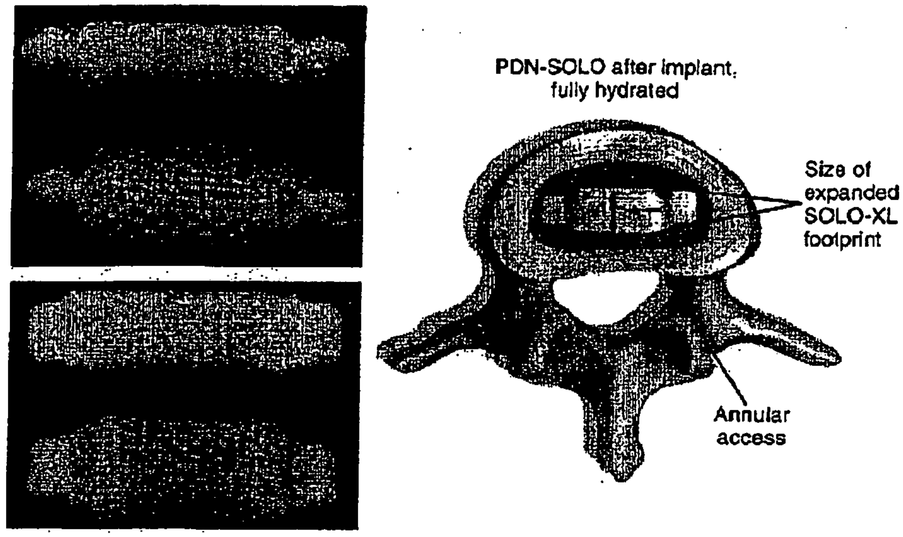



Fig. 40-6 A, Insertion of the PDN. A robust No. 0 or No. 1 suture is usually sewn through the distal upper portion of the jacket to be used to apply traction during PDN positioning. The need for this suture depends on the ease of PDN insertion; the tighter the opening the more likely the suture will be needed, as shown in the following illustrations. A flexible metal guide is placed quite ventrally in the cavity. B, As the PDN is driven along the guide into the empty nucleus cavity, traction on the suture aids in its transverse positioning. C-arm fluoroscopy is then used to determine the anterior-posterior and lateral position of the PDN, visualizing the small platinum-iridium markers in each PDN. Adjustments of the transverse position can be made with various probing instruments; the traction suture may be helpful here as well.

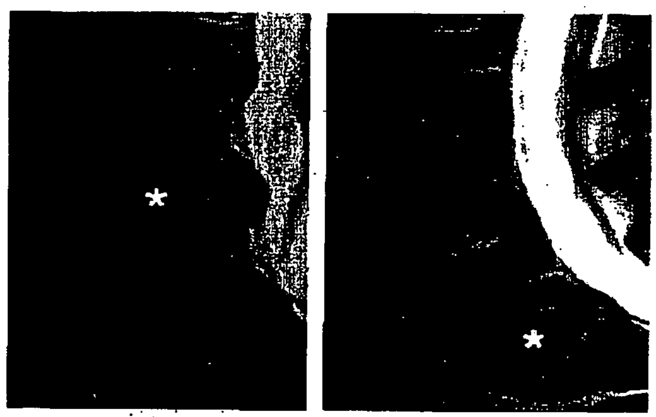
A




B

Fig. 40-7 After the SOLO device is positioned, it will begin to swell, locking into position. A, Photograph showing the relative sizes of the dehydrated (*upper*, at implant) and hydrated (*lower*, after more than 2 days of swelling) devices. B, The single SOLO expands laterally to about 75% of one of the original paired PDNs, distributing the endplate forces.

A



B

Fig. 40-8 Coronal MRI sections, T2-weighted images, from two patients (a male [A] and a female [B]) taken 6 months after PDN-SOLO implantation. Note that the fully hydrated PDN rather closely resembles normal nuclei in these now-asymptomatic patients. The preoperative MRI scans were typical, painful "black discs." The annulotomy tracts are healed but some residual new fibrosis is seen in the tracts—these are not high-intensity zone (HIZ) radial tear edema findings in these asymptomatic cases. Minor Modic type 2 changes are seen. The endplates are intact. * = Location of platinum-iridium markers in each patient.

## PATIENT SELECTION

Appropriate patient selection and preoperative planning are additionally essential to successful outcomes. Patients selected in the study are between 18 and 65 years of age, have one level of painful DDD generally confirmed by magnetic resonance imaging (MRI), and might or might not have a disc herniation. Although signs of degeneration may have been seen at multiple levels, only one of these levels should be symptomatic, which is sufficient to require surgical intervention. Nonoperative, conservative treatment should have been tried for 6 months or longer but failed to relieve the symptoms (severe low back pain with or without leg pain). Other less selective clinical manifestations may also be present, such as frank spinal instability, abnormal neurologic findings, diminished range of segmental motion, muscle spasms, spinal deformities, or vertebral bony changes.

## RESULTS

The mechanically and biologically well-proved PDN device is achieving the desired effects in cases of DDD, namely, restoration of disc height and mobility, restoration of segmental function and stability, and reduction in segmental pain without the need for a fusion.

A feasibility trial was begun in 1986, together with the author and Professor Robert Schönmayr, in Wiesbaden, Germany. In this trial, 16 patients were implanted with the original dual-implant PDN device design, using the initial surgical technique. Over the next 2 years, an additional 57 patients had the device pairs implanted at sites in Sweden, Saudi Arabia, Egypt, and the United States. New device modifications and techniques evolved, based on the limited international cohort. Initially, the device displacement rate was an unacceptable 37.3%, about two thirds of which required reoperation. This displacement, usually partial, was the single most important consideration during these trials, although no patient had more than temporary root compression effects, much like a herniated disc. At the same time, device efficacy showed an encouraging very positive improvement from baseline, as indicated using the Oswestry Disability Scale, the Prolo Economic Functioning Scale, the 11-Point Visual Analog Scale, and medial disc height measurements.[9] In addition, among the patients available at more than 8 years postoperatively, the flexion/extension studies showed the preservation of 5 to 8 degrees of segmental motion. In early 1999, a significant redesign of device geometry, the patient and device selection criteria, surgical technique, and postoperative patient rehabilitation was implemented. The number of successful outcomes rose with these improvements even though the guiding samples were small.

Further, in 1999, two new trials began under European Standard regulations: one in Sweden and the other, a multicenter study, in Germany. A Concordance European (CE) mark was obtained in August 1999, after which evaluations were concurrently undertaken in other countries. Data from the new 1999-2000 European trials have shown a dramatic reduction in the incidence of displacement as well as continuing good clinical results. If device movement did occur, it was within the first 6 months after implantation, usually before 4 months. Thus, when comparing outcome to preoperative baseline results, the 6-month postoperative follow-up results from these two European controlled clinical trials have shown that, on average, patients almost immediately experience a 64% improvement in their ability to function as measured by the Oswestry scale; a parallel 63% improvement in perceived pain was estimated by the 11-Point Visual Analog Scale, and an improvement of 22% in the median disc height over the preoperative measurements. Further, 85% of the patients required no additional intervention, and the dislodgement of a PDN was limited to a 6.4% rate. In the patients initially having herniated discs, no reherniations have been seen.

In 2001, a new singular PDN design was developed, the PDN-SOLO. This device, implanted as a single unit, markedly simplified the overall procedure and reduced the displacement rate to approximately 1%. It is only about 20% larger in dehydrated size than one of the original PDN pairs, but on hydration expands both vertically and horizontally to occupy about 75% of the size of the prior combined pair. Indeed, with a PDN-SOLO-XL (extra large), the hydration expands the device to fill more than 75% of the available nucleus cavity. Approximately 1500 SOLO implants were performed in 2003, and an additional 2000 were performed in 2004 and early 2005. The number of cases is rising, the percentage of displacements is falling, and the clinical results are improving with the PDN-SOLO